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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/384,957	03/10/2003		David Miller	2663/102	3368
20995	7590	06/30/2004		EXAM	INER
KNOBBE	MARTE	NS OLSON & BEA	AR LLP	SCHWARTZ, JO	ORDAN MARC
2040 MAIN FOURTEEN				ART UNIT	PAPER NUMBER
IRVINE, C				2873	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

KROBUE, MARTENS, DESCH & LEAF, ELF

ORANGE COUNTY DOCKETING JUL 0.7 2004

		Application No.	Applicant(s)	,
		10/384,957	MILLER ET AL.	ø
	Office Action Summary	Examiner	Art Unit	
		Jordan M. Schwartz	2873	
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with the	correspondence a	ddress
THE - Extensite after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (8) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a rep to period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tily within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDON	mely filed ys will be considered time in the mailing date of this ED (35 U.S.C. § 133).	ely. communication.
Status				
1)⊠	Responsive to communication(s) filed on 09 A			
	7	s action is non-final.		
3)	Since this application is in condition for allows			ne merits is
	closed in accordance with the practice under	Ex рапе Quayle, 1935 C.D. 11, 4	153 U.G. 213.	
Disposit	ion of Claims			
4)🛛	Claim(s) 1-10,32 and 108-160 is/are pending			
	4a) Of the above claim(s) 126,132-151,154 ar	ad 157 is/are withdrawn from con	sideration.	
,	Claim(s) is/are allowed.			
-	Claim(s) <u>1-10,32,108-125,127-131,152,153,1</u>	55,156,158 and 159 Israre reject	ea.	
	Claim(s) <u>160</u> is/are objected to. Claim(s) are subject to restriction and/	or election requirement.		
	tion Papers			
	The specification is objected to by the Examin		to by the Evernin	or
10)⊠	The drawing(s) filed on 10 March 2003 is/are: Applicant may not request that any objection to the			
	Replacement drawing sheet(s) including the corre			
111	The oath or declaration is objected to by the E			
•	under 35 U.S.C. § 119		(a) (d) ar (f)	
•	Acknowledgment is made of a claim for foreig	In priority under 35 U.S.C. § 119((a)-(a) or (i).	
a	1. Certified copies of the priority docume	nts have been received.		
	2. Certified copies of the priority document		ation No	
	3. Copies of the certified copies of the pri			al Stage
	application from the International Bure			
*	See the attached detailed Office action for a lis	st of the certified copies not recei	ved.	
Attachme	nt(s)			
1) 🛛 Not	ice of References Cited (PTO-892)	4) Interview Summa		
3) 🛛 Info	ice of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 er No(s)/Mail Date <u>4/9/04</u> .	Paper No(s)/Mail 5) Notice of Informa 6) Other:		PTO-152)

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-10, 32, 108-125, 127-131, 152-153, 155-156, 158-160 in the Election received April 9, 2004 is acknowledged.

Claim Rejections - 35 USC § 112

Claims 122-123, 128-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 122-123, that part of the claim stating "wherein the bio-compatible material" renders the claim vague and indefinite because independent claim 110 from which these claims depend has not claimed that the ophthalmic device comprises a bio-compatible material. Apparently the dependency of these claims is incorrect. It is therefore not clear as to which claim these claims were intended to depend from and therefore it is not clear if applicant is claiming that the optic comprises the claimed bio-compatible material, if the ophthalmic device comprises the claimed bio-compatible material, or if some other meaning is intended. For all of the aforementioned reasons, these claims are vague and indefinite. For purposes of examination it is assumed that both claims 122 and 123 meant to depend from claim 121. If applicant amends the dependency of the claims it is suggested that the claims be reviewed carefully to avoid duplicate claims.

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With respect to claims 128-129, that part of the claim stating "wherein the aperture includes" renders the claim vague and indefinite because claim 126 from which these claims depend has not claimed that the ophthalmic device comprises an aperture. Apparently the dependency of these claims is incorrect. It is therefore not clear as to which claim these claims were intended to depend from rendering these claims vague and indefinite. For purposes of examination it is assumed that both claims 128 and 129 meant to depend from claim 127. If applicant amends the dependency of the claims it is suggested that the claims be reviewed carefully to avoid duplicate claims.

Claim Objections

Claim 160 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, claim 160 has not been further treated on the merits.

Claim 124 is objected to for the following reason. Since the intended meaning could be determined from the specification and the Figures, a 112 rejection was not made but instead this lack of clarity issue is being raised in the following claim objection. Claim 124 states "wherein the medical grade polymer" while claim 123 from which this claim depends claims "comprising a medical polymer". From what is set forth in the other claims and in the specification, the assumed meaning is "medical polymer" and it is suggested that applicant delete the word "grade" to provide the necessary consistency. Appropriate correction is required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 32, 108-109, 127-131, 158-159 are rejected under 35 U.S.C. 102(b) as being anticipated by WO95/08135.

WO95/08135 reads on these claims by disclosing the limitations therein including the following: an ophthalmic lens comprising a lens body with an optic located in the lens body (abstract, page 14, lines 20-25, Figure 5, with the "annular mask portion 18" and "transmissive portion 29" being considered as the "optic"); a pin-hole like aperture substantially in the center of the optic (abstract, page 8, line 36, Figures 1, 4, 5 re aperture "20"). WO95/08135 further discloses that the annular mask portion i.e. the "optic" can be configured to produce diffraction (page 14, lines 29-33). Since the optic is configured to produce diffraction, it will inherently produce light interference, this being reasonably based upon it being well known that diffraction patterns are produced by light wave interference as well as being based upon the definition of the term "diffraction". Specifically, diffraction is defined as "As a wavefront of light passes by an opaque edge or through an opening, secondary weaker wavefronts are generated, apparently originating at that edge. These secondary wavefronts will interfere with the primary wavefront as well as with each other to form various

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diffraction patterns" (as defined in Photonics Dictionary). In reference to claim 2, WO95/08135 discloses the optic configured as a pattern (Figure 4 and 5) and any pattern or any material will inherently be comprised of particles or of a set of particles. WO95/08135 further discloses that the aperture can include optical power for vision correction (page 10, line 29); the pinhole aperture having a diameter within the claimed range (page 3, line 36); the annular mask region i.e. the "optic" having an outer diameter within the claimed range (page 4, line 1); the optic composed of a material of varying degrees of opacity (page 12, lines 31-39); and the lens being used as a method to increase the depth of focus of the human eye (page 9, line 4). The material of the lens of WO95/08135 will inherently be bio-compatible and non-dissolving, this being reasonably based upon WO95/08135 disclosing the lens can comprise a flexible polymer material (page 3, line 31) as well as being based upon WO95/08135 disclosing the lens for use as a rigid or soft contact lens within an eye of a user (page 3, line 31).

Claims 1-2, 4-5, 7-10, 32, 127, 129-131, 158-159 are rejected under 35 U.S.C. 102(b) as being anticipated by Peyman patent number 5,964,748.

Peyman reads on these claims by disclosing the limitations therein including the following: an ophthalmic lens (column 22, lines 26-44 re the ocular implant has diffractive and refractive powers or having portions as a fresnel lens); comprising a lens body with an optic located in the lens body (column 22, lines 26-44, that part of the lens that surrounds the center opening being the "optic"); a pin-hole like aperture substantially in the center of the optic (Figures 60-61, column 22, line 30). The optic of Peyman will inherently produce light

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interference, this being reasonably based upon Peyman disclosing the surrounding optic portion "utilizing diffractive technology" such as being "a Fresnel lens" (column 22, line 33). In reference to claims 2, any material will inherently be comprised of a pattern or a set of particles. Peyman further discloses the aperture having a diameter within the claimed range (column 22, lines 55-58); the annular mask region i.e. the "optic" having an outer diameter within the claimed range (column 22, lines 55-58); the optic composed of a biocompatible non-dissolving material (column 17, lines 6-17, column 23, lines 4-11); the material including either PMMA or a medical polymer (column 17, lines 6-17, column 23, lines 4-11). The optic of Peyman would inherently increase the depth of focus, this being reasonably based upon Peyman disclosing the optic to correct the focus of light (column 22, line 33) which would inherently include the depth of the focus of light.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 32, 108-109, 127-131, 158-159 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/08135 in view of Grant patent number 3,578,850.

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In reference to these claims, WO95/08135 discloses as is set forth above and it is believed that the "optic" would inherently produce interference of light as set forth in the rejection above. Regardless, Grant teaches that in a contact lens having a central transparent portion surrounded by an opaque portion (column 2, lines 44-65), similar to WO95/08135, that it is desirable to have the opaque portion configured to produce light interference for the purpose of avoiding flare or ghosting (column 2, lines 44-65). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the masking portion of WO95/08135 as being configured to produce light interference since Grant teaches that in a contact lens having a central transparent portion surrounded by an opaque portion, that it is desirable to have the opaque portion configured to produce light interference for the purpose of avoiding flare or ghosting.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/08135 in view of Anton et al patent number 5,314,961.

In reference to these claims, WO95/08135 discloses as is set forth above but does not specifically disclose the lens as being formed of either a PMMA material or a medical polymer. However, WO95/08135 does disclose that the lens can be formed of an oxygen permeable material or of a polymer material to form a rigid or soft contact lens (page 3, lines 31 and page 10, line 15). Anton et al teaches that contact lenses can be formed of PMMA material in order to provide a contact lens that is easily machinable (column 3, line 33) or from a medical polymer in order to provide a contact lens having increased oxygen

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permeability (column 6, line 20). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the contact lens of WO95/08135 formed of either a PMMA or medical polymer material since Anton et al teaches that contact lenses can be formed of PMMA material in order to provide a contact lens that is easily machinable or from a medical polymer in order to provide a contact lens having increased oxygen permeability.

Claims 152-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman patent number 5,964,748.

In reference to these claims, Peyman discloses as is set forth above including the optic being formed as a Fresnel lens (column 22, line 33) but does not specifically disclose the Fresnel lens as a series of opaque concentric circles. The examiner takes Judicial Notice that it is well known in the art of lenses for Fresnel lenses to be formed of opaque concentric circles for the purpose of providing the desired interference effect. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to the Fresnel lens optic of Peyman in the form of opaque concentric circles since it is well known in the art of lenses for Fresnel lenses to be formed of opaque concentric circles for the purpose of providing the desired interference effect.

Double Patenting

Claims 1-10, 32, 108-125, 127-131, 152-153, 155-156, 158-159 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of Patent Number 6,554,424.

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Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Patent 6,554,424 discloses an ophthalmic lens comprising an optic configured to produce light interference and a pin-hole like aperture substantially in the center of the optic (claims 1 and 20); the optic configured as a pattern of particles (claim 20); the pin-hole aperture including an optical power (claim 4); the pin-hole aperture having a diameter within the claimed range (claim 5); the optic having an outer diameter within the claimed range (claim 6); the optic composed of a material of varying degrees of opacity (claim 7); the optic composed of a bio-compatible, non-dissolving material (claim 9); the material as PMMA (claim 10); the material as a medical polymer (claim 11); the method for increasing depth of focus comprising an ophthalmic lens with an optic configured to produce interference and a pin-hole like aperture substantially in the center of the optic (claim 21); the optic to produce negative interference of diverging light reaching the optic (claim 1); the optic configured as a series of concentric circles (claim 15); the optic configured as a weave (claim 16).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

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USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Prior Art Citations

Parker et al publication number 2004/0047014 is being cited herein to substantiate the examiner's Judicial Notice that it is well known in the art of lenses for Fresnel lenses to be formed of opaque concentric circles for the purpose of providing the desired interference effect (paragraphs 0007-0009).

Neefe patent number 4,639,105 is being cited herein to show another reference that would have read on a number of the above rejected claims, however, such rejections would have been repetitive.

Allowable Subject Matter

Claims 110-121, 124-125 and 155-156 are allowed (upon overcoming the double patenting rejection set forth above and with claim 155 being written in independent form).

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Claims 122-123 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: with respect to the allowable subject matter, none of the prior art either alone or in combination disclose or teach of the claimed combination of limitations to warrant a rejection under 35 USC 102 or 103. Specifically, with reference to claims 110-125, none of the prior art either alone or in combination, disclose or teach of the claimed ophthalmic device for application to an eye of a patient comprising the optic configured to produce interference of light reaching the optic, an aperture disposed within the optic, the ophthalmic device increasing the depth of focus of the eye, and specifically including, as the distinguishing feature in combination with the other limitations, the claimed optic configured to produce negative interference of diverging light reaching the optic. . Specifically, with reference to claims 155-156, none of the prior art either alone or in combination, disclose or teach of the claimed ophthalmic device configured to be applied to an eye of a patient comprising an optic configured to produce interference, an aperture substantially in the center of the optic, and specifically including, as the distinguishing feature in combination with the other limitations, the claimed optic comprising a weave.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number

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is (571) 272-2337. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (571) 272-2328. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jordan M. Schwartz Primary Examiner Art Unit 2873 June 24, 2004

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APR 0 9 2004 E BY APPLICANT	APPLICANT David Miller, et al.	
(USE GENERAL SHEETS IF NECESSARY)	FILING DATE March 10, 2003	GROUP 2873

			U.S. PATENT DOCUMENTS		•	
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
91	3,270,099	08/30/66	CAMP	264	18	
4	3,507,586	04/21/70	KNAPP	351	KOK	
91	3,578,850	05/18/71	GRANT	351	KOR	
91	3,726,587	04/10/73	KENDALL	351	16	,
1	3,794,414	02/26/74	WESLEY	351	161	
91	. 4,639,105	01/1987	NEEFE	351	162	•
41	4,655,774	04/07/87	CHOYCE	623	5.11	
W	4,955,904	09/11/90	ATEBARA ET AL.	623	611	
41	4,976,732	12/11/90	VOROSMARTHY	623	L.19	
47	4,994,080	02/19/91	SHEPARD	623	6.64	
07	5,196,026	03/23/93	BARRETT ET AL.	125	FEY	
VI I	5,245,367	09/14/93	MILLER ET AL.	351	161	
4	5,260,727	11/9/93	OKSMAN ET AL.	351	162	
4	5,314,961	05/1994	ANTON ET AL.	525	240	
01	5,662,706	09/02/97	LEGERTON ET AL.	623	5.17	
·01	5,628,794	05/13/97	LINDSTROM	623	6.21	·
41	5,757,458	05/26/98	MILLER ET AL.	351	42	
.01	5,786,883	07/28/98	MILLER ET AL.	351	162	
01	5,864,378	01/26/99	PORTNEY	351	KOR	
91	5,905,561	05/18/99	LEE ET AL.	623	6.31	
41	5,964,748	10/12/99	PEYMAN .	606		
01	5,965,330	10/12/99	EVANS ET AL.	430	321	
4/	5,980,040	11/09/99	XU ET AL.	351	142	
Q.	6,090,141	07/18/00	LINDSTROM	62	5.11	
21	6,554,424	04/29/03	MILLER ET AL.	623	6.31	

EXAMINER //

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	PE		SHEET 2 OF
١.	FORM POD 1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT	ATTY, DOCKET NO. ACUFO.002DV1	APPLICATION NO. 10/384,957
1	BY APPLICANT	APPLICANT David Miller, et al.	
•	(USE SEVERAL SHEETS IF NECESSARY)	FILING DATE March 10, 2003	GROUP 2673

			FOREIGN PATENT DOCUMENTS		•		
EXAMINER	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
INITIAL						YES .	NO
970	WO 95/08135	03/23/95	MILLER ET AL.	~	-		
双	WO 97/48005	18/12/97	LEGERTON ET AL.				

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
W.	"RESEARCH ON THE MULTI-RANGE LENS," WESLEY, N.K., PAGES 18-24.
21	"IMPLANTS WITH COLOURED AND OPAQUE PORTIONS: IMPLANTS WITH BUILT-IN STENOPEIC APERTURE," CHOYCE, P., PAGES 21-26; "UNIOCULAR APHAKIA CORRECTED BY ANTERIOR CHAMBER IMPLANTS WITH BUILT-IN STENOEIC APERTURE," P. CHOYCE., PAGES 132-136 INTRA-OCULAR LENSES AND IMPLANTS. London, 1964.
es	"USE AND INTERPRETATION OF THE PINHOLE TEST", <u>THE OPTOMETRIC WEEKLY</u> , TAKAHASHI, E., PAGES 83-86, 1965.
4	"NEW ASPECTS IN THE FITTING OF THE MULTI-RANGE BIFOCAL CONTACT LENS", J.J. GROPPI, <u>CONTACTO</u> , VOLUME 15:22-29, 1971.
9,1	"THE CONTROLLED-PUPIL CONTACT LENS IN LOW VISION PROBLEMS", JOURNAL OF THE AMERICAN OPTOMETIC ASSOCIATION, ROSENBLOOM, PAGES 836-840, 1969.
9,	"HOLES IN CLEAR LENSES DEMONSTRATE A PINHOLE EFFECT", ARCHIVES OF OPTHAMOLOGY, ZACHARIA ET AL., PAGES 511-513, 1988.
3/	*QUANTIFICATION OF THE PINHOLE EFFECT*, <u>PERSPECTIVES IN REFRACTION</u> , VOLUME 21:347-350, MILLER ET AL., 1977.
. 8/	EPO PARTIAL SEARCH REPORT, DATED 08/18/2000.
20	PCT/US 00/05136 INTERNATIONAL PRELIMINARY EXAMINATION REPORT, DATED 03/15/01.

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		Notice of References Cited					Application/Control 10/384,957	No.	Applicant(s)/Pat Reexamination MILLER ET AL.	1
	. •	Notice of References Cited		ŀ	Examiner		Art Unit	B4-44		
				ļ	Jordan M. Schwar	tz	2873	Page 1 of 1		
				U.S. PAT	ENT DOCUMENTS					
*		Document Number Country Code-Number-Kind Code	Date MM-YYYY		Na	me		Classification		
	Α	US-2004/0047014	03-2004	Parker e	t al.			359/015		
	В	US-								
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*	O P Q	Document Number Country Code-Number-Kind Code		C	buntry			Classification		
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